

K062432

### 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

<b>Submitter</b>	Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410	FEB 22 2007
<b>Contact</b>	Jacquelyn A. Hughes, RAC Director, Regulatory Affairs & Quality Assurance Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410 Tel. 561-776-6819 Fax. 561-514 6316 Email jhughes@3implant.com	
<b>Date Prepared</b>	August 18, 2006	
<b>Device Name</b>	NanoTite™ Dental Implants	
<b>Classification Name</b>	Endosseous Dental Implants	
<b>Device Classification</b>	Class II Dental Devices Panel 21 CFR § 872.3640	
<b>Predicate Devices</b>	3i OSSEOTITE Dental Implants K051461	
<b>Performance</b>	Performance standards have not been established by the FDA under Section 514 of the Federal Food, Drug and Cosmetic Act.	
<b>Device Description</b>	The NanoTite Dental Implants, hereinafter referred to as <i>NanoTite</i> Dental Implants, are the same dental implants referred to as “3i Nano CaP OSSEOTITE” Dental Implants, subject of the predict device submission K051461. The <i>NanoTite</i> Dental Implants are provided with the proprietary OSSEOTITE acid-etched surface further treated with a deposition of nanometer scale crystals of calcium phosphate. Implants are offered in	

0008

0009

both tapered and parallel-walled/straight designs, and each design provides offerings for either external hex or internal connections.

#### Indications for Use

3i dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

In addition, when a minimum of 4 implants,  $\geq 10$ mm in length, are placed in the maxilla and/or mandible and splinted in the anterior region, immediate loading is indicated.

#### Technological Characteristics

The design features and functions are similar to the currently available OSSEOTITE, OSSEOTITE NT, OSSEOTITE Certain, OSSEOTITE Certain NT, and Prevail Implants, and 3i Implant Innovations implants and cover screws. The OSSEOTITE surface is enhanced by the presence of nanometer scale crystals of calcium phosphate.

#### Performance Testing

Laboratory testing was conducted to determine device functionality and conformance to design input requirements, as well as FDA's *Class II special controls guidance document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*. Risk analysis was conducted in accordance with ISO 14971. Results from all of these tests were included in the premarket notification submission for the predicate devices, K051461.

Specific performance claims which are the subject of this premarket notification are based on reports contained in Sections 18 and 19.

#### Conclusion

The *NanoTite* Dental Implants are substantially equivalent to the dental implants described in the premarket notification submission for the predicate devices, K051461.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Jacquelyn A. Hughes  
Director, Regulatory Affairs & Quality Assurance  
Implant Innovations, Incorporated  
4555 Riverside Drive  
Palm Beach Gardens, Florida 33410

FEB 22 2007

Re: K062432  
Trade/Device Name: NanoTite™ Dental Implants  
Regulation Number: 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: II  
Product Code: DZE  
Dated: February 13, 2007  
Received: February 15, 2007

Dear Ms. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Page 2 – Ms. Hughes

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K062432

Device Name: NanoTite™ Dental Implants

Indications for Use:

3i dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

In addition, when a minimum of 4 implants,  $\geq 10$ mm in length, are placed in the maxilla and/or the mandible and splinted in the anterior region, immediate loading is indicated.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Kim Muley for MSR*

*K062432*

Page \_\_\_ of \_\_\_

0008